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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,700	06/26/2003	Chang-Hsing Liang	8024-004-US	5029

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EXAMINER	
PESELEV, ELLI	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 04/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/606,700	LIANG ET AL.	
	Examiner	Art Unit	
	Elli Peselev	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-9* is/are pending in the application.

4a) Of the above claim(s) *3 and 4* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 5-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This application contains claims 3-4 drawn to an invention nonelected with traverse in Paper filed on October 21, 2004. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The steps set forth in claim 9 are not disclosed or suggested by the specification as originally filed.

Claims 1 and 5-9 are rejected under 35 U.S.C. 112, first paragraph, for the reasons set forth in the Office Action of November 12, 2004.

Applicant's arguments filed February 16, 2005 have been considered but have not been found persuasive.

Applicant contends that the specification at page 110 (Table 1) identifies representative agents having antimicrobial potency and that the specification at pages 81-109 teaches the synthesis of said aminoglycoside compounds. The specification at pages 81-109 and Table 1 have been considered but have not been found persuasive.

For example, the instant claims encompass compounds wherein X1 and X2 are S or NH. The specification fails to show how to synthesize compounds wherein X1 and X2 are S or NH and fails to show that such compounds have any biological activity.

Further, the instant claims encompass compounds wherein all R6, R7, R8 and R9 are all disaccharides, which are all substituted by disaccharides, which are substituted by disaccharides, etc. The compounds encompassed by the instant claims read on structural formulas which are vastly different from the compounds shown on page 89-110 of the specification. Based on the instant specification, a person having ordinary skill in the art at the time the instant invention was made would not know how to synthesize a large proportion of the claimed compounds nor how to use the same.

Further, applicant contends that the claimed structures will have the ability to form complexes with negatively charged RNA, thereby disrupting a variety of therapeutically relevant targets involved in viral replication and that he 2-DOS ring system is known in the state of the art in the field to interfere with he ribosomal A-site, it is likely that the claimed compounds will effect gene expression. This argument has not been found persuasive. The only data presented in the specification on page 110, Table 1 relating to antibacterial activity. There is no evidence in the specification that he claimed compounds have any other biological activity including preventing a bacterial infection and treating, preventing or ameliorating a viral infection, a cancer or a genetic disorder. The statements presented by applicant are seen to be mere speculative and would require further research and undue experimentation to determine which of the claimed compounds have the activities encompassed by the instant claims. Further, the evidence relating to the treatment of bacterial infection does not support the claim to the prevention of bacterial infection. The term "preventing" encompass administration of the effective compound to a healthy host and preventing said host

from ever getting a bacterial infection i.e. it reads on vaccine. There is no evidence of record that the claimed compounds are effective as vaccines. Applicant contends that the term "preventing" does not imply vaccine. Said argument has not been found persuasive since the instant specification fails to define the term "preventing" and fails to provide any guidance or direction on how to chose subject which are in need of prevention of bacterial infections, viral infections, cancer or a genetic disorder. Note that there are no known drugs that are effective for preventing said diseases. Therefore, there is a good reason to doubt that the claimed compounds have any other biological activity, except the treatment of bacterial infections.

Claims 1 and 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is encompassed by the terminology "modified amino" and "modified hydroxyl". Modified how? I.e. the scope of the invention cannot be determined.

Regarding claim 1, the phrase "including" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

The term "comprising" (claims 1 and 5-9) renders the structural formula indefinite since it leaves said formula open-ended i.e. the scope of the invention cannot be determined.

It is not clear what is meant by the term "DOS" (claim 9).

It is not clear what is encompassed by the terminology "chemo-enzymatically" (claim 9). Further, the natural glycosyl donors and unnatural glycosyl donors" have not been defined in step (c) of the method set forth in claim 9.

Applicant's arguments filed February 16, 2005 have been considered but have not been found persuasive.

The specification on page 38 states that the term "modified amino" as used herein includes the terms "protected amino", "amine protecting group" and "carboxamido" and that the term "modified hydroxyl" as used herein includes the terms "protected hydroxyl", 'hydroxyl protecting group", "protected hydroxymethyl", "alkoxy", "aryloxy", "acyl", "carboxy esters", and "acyloxy". However, note that said definations employ the term "include" i.e. said definations are not limited to the moieties set forth but include any other moieties.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached on (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Elli Peselev

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